

REMARKS

Summary of the Office Action

The application was restricted to claims 50-56.

The application is not entitled to claim priority to provisional application no. 60/079,952 which was filed March 3, 1998.

Applicants are advised to review the accuracy of the inventors Oath and Declaration.

The disclosure is objected to because the statement in lines 6-8 of page 1 claiming priority to provisional application no. 60/079,952 refers to an application that expired prior to the filing of the instant application.

Claims 51-53, 55 and 56 stand rejected under 35 U.S.C. § 112, second paragraph.

Claims 50-56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,380,492 (*Seymour*).

Summary of the Response to the Office Action

Lines 6-8 of page 1 of the specification are amended by removing the priority claim to U.S. provisional application no. 60/079,952 and replacing it with a priority claim to U.S. application serial no. 09/292,293.

Pursuant to the Examiner's advised review of the oath/declaration, a copy of the assignee's company merger documents filed in U.S. Application serial no. 09/292,293 and the PTO recordation form from the parent case are enclosed for the Examiner's consideration.

Claims 50-56 are amended and new claims 57-61 are added.

Examiner's Telephone Interview

The undersigned wishes to thank the Examiner for the courtesies extended during the Examiner's telephone interview of January 7, 2003. During the interview, the undersigned provided a brief description of the invention, followed by a description of the *Seymour* reference. In particular, it was noted that *Seymour*'s device discloses a system for collecting a sample that includes a sample adequacy indicator, but nowhere does this reference teach or suggest an integrated sample collector and assay device housing a lateral flow assay strip. No agreement was reached.

Restriction/Election to claims 50-56

Applicants' election of claims 50-56 for examination is affirmed.

The priority statement

The present application is a divisional application of U.S. application serial no. 09/292,293, now U.S. Pat. No. 6,303,081 which issued on October 16, 2002. Lines 6-8 of page 1 of the disclosure stand objected to because it contains a priority claim to a now abandoned provisional application 60/079,952. Applicants have amended the first paragraph of page 1 of the specification as follows:

This application is a divisional of U.S. Application No. 09/292,293, filed April 15, 1999, now U.S. Pat. No. 6,303,081 [continuation-in-part of, and claims priority from, U.S. Provisional Patent Application No. 60/079,952, filed March 3, 1998,].

By this amendment, Applicants submit that this divisional application contains a proper priority statement. Removal of the objection to the disclosure is earnestly solicited.

The rejections under 35 U.S.C. § 112, second paragraph

Claims 51-53, 55 and 56 stand rejected to because they depend from a canceled claim. Applicants have amended claims 51-53 to depend from claim 50 and claims 55 and 56 to depend from claim 54. Removal of the rejections to claims 51-53 under 35 U.S.C. § 112 is earnestly solicited.

Claim 55 stands rejected because there is no antecedent basis for "wicking member second part." Applicants have amended claim 55 to address this typographical error in claim 55 by changing "part" to "portion", as was clearly originally intended. Accordingly, the changing of "wicking member second part" to "wicking member second portion" is not necessary in order for claim 55 to meet the requirements of 35 U.S.C. § 112, second paragraph, since it is clear that the antecedent basis for "second part" is "second portion." Removal of the rejection to claim 55 under 35 U.S.C. § 112 is earnestly solicited.

Claim 56 stands rejected because it is believed that the phrase "the neck portion tapers from the narrow end width to the opening width" is unclear. The Examiner states that the word taper, in the context of the claim, means "gets larger." Although Applicants believe that the meaning of claim 56 is clear, and therefore no amendment is needed in order for claim 56 to comply with the requirements of 35 U.S.C. § 112, Applicants have nevertheless amended claim 56 in order to expedite allowance by replacing "the neck portion tapers from the narrow end width to the opening width" with --the neck portion tapers from the opening width to the narrow end width--.

The rejections under 35 U.S.C. § 102(b)

Claims 50-56 stand rejected in view of *Seymour*. Applicants traverse this rejection for the following reasons.

Original claims 50 and 54 include the limitation of a lateral flow assay strip, which is not taught or suggested by *Seymour*'s sampling system and sample adequacy system. The Office Action appears to conclude that elongate member 416 is a lateral flow assay strip. *Seymour* discloses a sample collector that includes a sample adequacy indicator, e.g., sample adequacy system 414, which is used to indicate when a sufficient fluid sample has been collected. There is nothing in *Seymour*'s device that is even remotely similar to a lateral flow assay strip, as this term is defined in the specification. Accordingly, Applicants believe that claims 50 and 54 comply with the requirements of 35 U.S.C. § 102(b) without amendment. Nevertheless, Applicants have amended claims 50 and 54 in order to expedite allowance by including the phrase "the assay strip containing at least one reagent that is used to detect one of the absence and presence of an analyte in a fluid." By this amendment, Applicants do not narrow the scope of claims 50 and 54 because one of ordinary skill in the art would have readily concluded that the phrase "lateral flow assay strip" implied the aforementioned meaning *without the need for the amendment*.

For the above reasons, Applicants respectfully request that the rejections of claims 50 and 54 under 35 U.S.C. § 102(b) be removed. Allowance of claims 50 and 54 is earnestly solicited.

Claims 51-53 and 55-56, and new claims 57 and 58 depend from allowable claims 50 and 54, respectively, and recite limitations which further distinguish Applicants' invention from the

art of record. For either of these reasons, removal of the rejections under 35 U.S.C. § 102(b) for claims 51-53 and 55-56, and allowance of claims 51-53 and 55-61 is earnestly solicited.

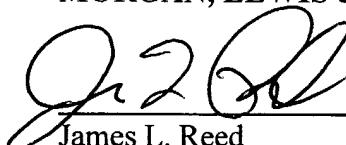
CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration and the timely allowance of the pending claims. **Should the Examiner feel that there remains any matters outstanding before a Notice of Allowance may issue, the Examiner is invited to contact Applicants' undersigned representative at 202-739-5772.**

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please amend the first paragraph of page 1 of the specification as follows:

This application is a divisional of U.S. Application No. 09/292,293, filed April 15, 1999, now U.S. Pat. No. 6,303,081 [continuation-in-part of, and claims priority from, U.S. Provisional Patent Application No. 60/079,952, filed March 3, 1998,].

IN THE CLAIMS:

Please amend claims 50-56 as follows:

50. **(Amended)** A device for collecting and assay of fluids, comprising:
 - a housing having a fluid receiving end and an assay portion;
 - a lateral flow assay strip contained substantially within the assay portion, the assay strip containing at least one reagent that is used to detect one of the presence and absence of at least one analyte in a fluid; and
 - a collection strip for transporting the fluid from a fluid source to the assay strip, the collection strip including:
 - a first, narrow end contained within the housing and in fluid communication with the assay strip, and
 - a second, enlarged end protruding from the fluid receiving end.
51. **(Amended)** The device of claim 50 [1], wherein the collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a fluid source to the assay strip.
52. **(Amended)** The device of claim 50 [1], wherein the fluid source is an oral cavity.
53. **(Amended)** The device of claim 50 [1], wherein the second end is one of a paddle-shape and substantially bulbous shape.

54. **(Amended)** A device for assay of oral fluid, comprising:

an assay portion housing a lateral flow assay strip, the assay strip containing at least one reagent that is used to detect one of the presence and absence of at least one analyte in a fluid;
and ;

a neck portion extending from the assay portion, the neck portion forming a channel for delivery of fluid to the assay strip, the channel being defined by a first, narrow part proximal to the assay portion and a second part including an opening for receiving the oral fluid, wherein the second part includes a channel width that is substantially wider than the channel width at the narrow end;

a wicking member in fluid communication with the lateral assay strip, the wicking member having a first portion disposed within the channel and a second portion protruding outwardly from the neck portion opening.

55. **(Amended)** The device of claim 54 [5], wherein the wicking member second portion [part] is paddle shaped.

56. **(Amended)** The device of claim 54 [5], wherein the width of the neck portion tapers from the [narrow end width to the opening width] opening width to the narrow end width.

New claims 57-61 have been added.